STERIS®

510(k) Summary
For
Amsco® V-PRO™ MAX Low Temperature Sterilization System

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Summary Date: July 27, 2011

1. Device Name

Trade Name:	Amsco® V-PRO™ MAX Low Temperature Sterilization System
Common/usual Name:	Vapor Phase Hydrogen Peroxide Sterilizer
Classification Name:	Sterilizer, Ethylene Oxide Gas 21 CFR 880.6860 Product Code MLR

2. Predicate Devices

Amsco® V-PRO™ 1 Low Temperature Sterilization System (K062297)
Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System (K083097)
STERRAD® NX Sterilizer (K042116)
TSO3 STERIZONE® 125L Sterilizer (K090636)

3. Description of Device

The Amsco V-PRO MAX Low Temperature Sterilization System is a new sterilizer model to be added to the Amsco V-PRO family of sterilizers. The V-PRO product line currently consists of the Amsco V-PRO 1 and Amsco V-PRO 1 Plus Sterilizers.

The V-PRO MAX Sterilizer has three pre-programmed cycles: the Lumen Cycle (K062297), the Non Lumen Cycle (K083097) and the Flexible Cycle (subject of this submission). The V-PRO MAX Low Temperature Sterilization System is intended for terminal sterilization of cleaned, rinsed, dried and packaged reusable surgical instruments used in healthcare facilities.

The V-PRO MAX Sterilizer uses VAPROX HC Sterilant to sterilize the intended devices through exposure to vaporized hydrogen peroxide (VHP). Its three pre-programmed cycles all utilize a conditioning phase, a sterilization phase and an aeration phase. The packaged sterilized devices are ready for use at the completion of the cycle; no cool down or aeration period is required.

The Flexible Cycle has been designed to sterilize surgical flexible endoscopes (such as those used in ENT, Urology and Surgical care) and bronchoscopes. The flexible endoscopes can be single or dual channeled and they may be processed in a flexible endoscope-only load or in combination with non-lumened medical instruments. The cycle is approximately 35 minutes long.

The Verify V24 SCBI (K073244 and K09051), Verify VH2O2 Process Indicator (K091174), V-PRO Sterilization Trays (K070769), and Vis-U-All Tyvek pouches

(K070765, K071087, and K090371) have been validated for use in the V-PRO MAX Sterilizer.

4. Intended Use

The Amsco V-PRO MAX Low Temperature Sterilization System, with VAPROX™ HC Sterilant, is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in healthcare facilities. The three pre-programmed sterilization cycles (Lumen Cycle, Non Lumen Cycle, and Flexible Cycle) operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

The Amsco V-PRO MAX Low Temperature Sterilizer System's **Lumen Cycle**, cleared under K062297, can sterilize:[a]

- Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Medical devices, including rigid endoscopes, with a single stainless steel lumen with:
  - an inside diameter of 1 mm or larger and a length of 125 mm or shorter
  - an insider diameter of 2 mm or larger and a length of 250 mm or shorter
  - an inside diameter of 3 mm or larger and a length of 400 mm or shorter

[a] The validation testing for all lumen sizes was conducted using a maximum of twenty (20) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.

The Amsco V-PRO MAX Low Temperature Sterilization System's **Non Lumen Cycle,** cleared under K083097, can sterilize:[b]

Non-lumened instruments including non-lumened rigid endoscopes and non-lumened instruments with stainless steel diffusion-restricted areas such as the hinged portion of forceps or scissors.

[b] The validation studies were conducted using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.

The Amsco V-PRO MAX Low Temperature Sterilization System's **Flexible Cycle,** the subject of this submission, can sterilize single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical care) and bronchoscopes in either of two load configurations:

1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load.[c]

The flexible endoscopes may contain either:
- a single lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter
- or two lumens with:
  - one lumen having an inside diameter of 1 mm or larger and a length of 998 mm or shorter
  - and the other lumen having an inside diameter of 1 mm or larger and a length of 850 mm or shorter

[c] The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).

2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors.[d]

   The flexible endoscope can contain either:
   - a single lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter
   - or two lumens with:
     - one lumen having an inside diameter of 1 mm or larger and a length of 998 mm or shorter
     - and the other lumen having an inside diameter of 1 mm or larger and a length of 850 mm or shorter

   [d] The validation studies were conducted with a flexible endoscope in a tray with silicone mat and light cord (if not integral to endoscope). Also included in the load were an additional instrument tray and one pouch for a total load weight of 24.0 lbs.

5. Summary of Nonclinical Tests

The Amsco V-PRO MAX Low Temperature Sterilization System has the same or similar intended use and the same technological characteristics as compared to the predicate devices. Performance testing to assess and demonstrate substantial equivalence to the predicates is summarized below.

Test	Result	Conclusion
AOAC Sporicidal Test	All 720 carriers processed using 3 lots of EOSL sterilant were sterile.	PASS
Determination of D-value and Total Kill Endpoint	Greater than a 12 log reduction of the most resistant organism is achieved within the Flexible Cycle sterilant exposure time.	PASS
½ Cycle Modified Total Kill Endpoint Verification	Modified total kill end point analysis was demonstrated. The standard injection weight of 2.1 g and a lower injection weight of 1.457 g resulted in all sterile results for both validation loads. All survival results were shown at the lowest weight evaluated, 0.121 g. Partial positives results were seen at the intermediate injection weights.	PASS
½ Cycle Sterilization Verification of Lumen Claims	The V-PRO Flexible Cycle reproducibly sterilizes 1 x 1050 mm lumens under worst case conditions in a V-PRO Flexible ½ Cycle	PASS
½ Cycle Verification of Mated Surfaces	Sterile efficacy was demonstrated for mated surfaces packaged in a double-wrapped tray or in a double-pouch configuration under worst case conditions in a V-PRO Flexible ½ Cycle	PASS
½ Cycle Verification of Non Mated Surfaces	Sterile efficacy was demonstrated for non mated surfaces packaged in a double-wrapped tray under worst case conditions in a V-PRO Flexible ½ Cycle	PASS
Simulated Use Test	Simulated use testing verified the ability of the V-PRO Flexible Cycle to sterilize flexible endoscopes and non lumened medical devices under worst case processing conditions.	PASS
In Use Test	The in use investigation demonstrated the ability of the V-PRO Flexible Cycle to sterilize clinically-cleaned, patient-soiled medical instruments.	PASS
Biocompatibility	Cytotoxicity and residue analysis of 23 materials have demonstrated biocompatibility after processing in the V-PRO MAX Sterilizer.	PASS
Medical Device Material Compatibility	Evaluation of medical devices after multiple cycles in the V-PRO MAX Sterilizer has demonstrated compatibility with 23 materials of construction.	PASS
Flexible Cycle Final Process Qualification	The V-PRO Flexible Cycle final process qualification was successful. All three lots of CI exhibited complete color change. All three SCBI PIs exhibited a passing color change and all SCBIs were negative for growth. Manual inspection of the process parameter data confirmed that all cycle specifications were met.	PASS

Test	Result	Conclusion
Validation of Accessories for use in the V-PRO Flexible Cycle		
Verify V24 SCBIs	Three lots of Verify V24 SCBIs were sterile (no growth) after processing in the V-PRO Flexible ½ Cycle.	PASS
Verify Vaporized VH2O2 Process Indicators	Three lots of Verify Vaporized VH2O2 Process Indicator exhibited a complete color change under worst case simulated use.	PASS
V-PRO Sterilization Trays	1 x 1050 mm lumens were successfully sterilized in the V-PRO Sterilization Trays under ½ cycle worst case conditions.	PASS
Vis-U-All Tyvek Pouches	Mated and non mated surfaces were successfully sterilized in the Vis-U-All Tyvek Pouches under ½ cycle worst case conditions	PASS

The V-PRO Accessories (Verify V24 SCBIs, Verify Vaporized VH2O2 Process Indicators, V-PRO Sterilization Trays and Vis-U-All Tyvek Pouches) are qualified for the Lumen, Non Lumen and Flexible V-PRO Sterilization Cycles.

The Amsco V-PRO MAX Low Temperature Sterilization System has been tested for conformity and is certified to the following standards:

- EN 61010-1:2001 Safety requirements for electrical equipment for measurement, control and laboratory use. General requirements; Part 1: General Requirements
- EN 60601-1-2:2002 Medical electrical equipment. General requirements for safety. Collateral standard. Electromagnetic compatibility. Requirements and tests.

6. Conclusion

The Amsco V-PRO MAX Low Temperature Sterilization System's Flexible Cycle has been validated to meet the established performance criteria. The results of the Amsco V-PRO MAX Low Temperature Sterilization System verification studies demonstrate that the Flexible Cycle performs as intended and the proposed device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Robert F. Sullivan
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5960 Heisley Road
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AUG 12 2011

Re: K102330
Trade/Device Name: Amsco® V-PRO ™ MAX Low Temperature Sterilization System
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: II
Product Code: MLR
Dated: July 27, 2011
Received: July 28, 2011

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devi
Office of Device Evaluation
Center of Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102330

Device Name: **Amsco® V-PRO™ MAX Low Temperature Sterilization System**

Indications For Use:

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[b] The validation studies were conducted using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.

The Amsco V-PRO MAX Low Temperature Sterilization System's **Flexible Cycle,** the subject of this submission, can sterilize single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of two load configurations:

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The parameters for the three V-PRO Cycles are as follows:

Sterilization Cycle	Sterilant injection (g)	# of Injections	Sterilant Exposure Time (min)	Chamber Pressure Prior to Injection (Torr)	Chamber/ Vaporizer Temperature (°C)
Lumen	2.1	4	32	0.4	50/60
Non Lumen	2.1	4	12	1	50/60
Flexible	2.1	4	12	0.4	50/60

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102330